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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MUTUAL PHARMACEUTICAL COMPANY, INC., et al., Plaintiffs, v. WATSON PHARMACEUTICALS, INC., et al., Defendants.	Civil Action No. 09-5421(GEB)(TJB) **DECLARATION OF GREGORY K. HAYER IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANT WEST-WARD PHARMACEUTICAL CORP.'S MOTION FOR SUMMARY JUDGMENT**

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I, Gregory K. Hayer, declare and state as follows:

1. I am the Senior Vice President of Business Development and Market Access for Mutual Pharmaceutical Company, Inc. ("Mutual") and AR Scientific, Inc. ("AR Scientific") (referred to collectively with related company AR Holding Company, Inc. as "Mutual").

2. I am of the age of majority and competent to give the testimony contained herein. The testimony herein is based on my own personal knowledge.

3. In June 2006, the United States Food and Drug Administration ("FDA") publicly announced a new drug safety initiative to remove unapproved drugs from the market.

4. In response to the FDA's new initiative, in July 2006 Mutual ceased all sales and distribution of unapproved drugs, including unapproved colchicine.

5. During the time that Mutual sold unapproved colchicine, there was no FDA-approved single ingredient colchicine product available on the market. There was no FDA-approved single ingredient colchicine product available until Mutual obtained FDA-approval for its COLCRYS® product.

6. In July 2006, I contacted the Price Lists and Wholesale Ordering Systems and informed them that Mutual had discontinued the sale of all unapproved products, including unapproved single ingredient 0.6 mg colchicine, and requested that all of Mutual's unapproved products, including unapproved colchicine, be removed from the Price Lists and Wholesale Ordering Systems.

7. Mutual has not shipped or sold a single unapproved drug, including unapproved single-ingredient 0.6 mg colchicine, since July 2006.

8. Mutual lost millions of dollars in potential profits by ceasing the sale of unapproved drugs, including unapproved colchicine, and incurred significant costs in terms of time, money, and resources to voluntarily remove its unapproved drug products from the market.

9. Shortly after July 2006, Mutual began the process of seeking FDA approval for a product containing colchicine as the sole active ingredient. The FDA review and approval process required a number of filings, clinical trials, and data assessment, which required a significant expenditure of time, money, and resources by Mutual.

10. In February 2007, Mutual submitted an Investigational New Drug application ("IND") for colchicine.

11. In September 2007, Mutual filed a Request for Orphan Drug Designation for colchicine for Familial Mediterranean Fever ("FMF").

12. In June 2008, Mutual submitted a New Drug Application ("NDA") for 0.6 mg tablets containing colchicine as the sole active pharmaceutical ingredient for the treatment of FMF.

13. Mutual also submitted another NDA in September 2008 for 0.6 mg tablets containing colchicine as the sole active ingredient for the treatment of gout flares.

14. Mutual filed a third and final NDA in November 2008 for 0.6 mg tablets containing colchicine as the sole active ingredient for the prophylaxis (prevention) of gout flares.

15. After over two years of providing information to the FDA and working to satisfy the many requirements necessary for FDA approval, at a cost of tens of millions of dollars, Mutual obtained the first of three FDA approvals for its COLCRYS® colchicine (0.6 mg) product in July 2009 for the treatment of FMF. This was followed by FDA approvals to market and sell COLCRYS® for the treatment of gout flares later in July 2009, and for the prophylaxis (prevention) of gout flares in October 2009.

16. Receiving FDA approval entitled Mutual to a seven-year period to exclusively market COLCRYS® for the treatment of FMF, and a three-year period to exclusively market COLCRYS® for the treatment of gout flares.

17. Part of the approval of Mutual's colchicine product involved the FDA's comprehensive review of several clinical studies sponsored by Mutual that demonstrated the safety and efficacy of COLCRYS®.

18. These clinical studies resulted in a number of significant findings about the use of colchicine and potential health hazards associated with the drug; information which had been previously unknown. These findings, incorporated into Mutual's Product Inserts and Labels, became publicly known and widely disseminated throughout the pharmaceutical community, included:

i. the development of new dosing regimens for COLCRYS® aimed at reducing the total amount of colchicine used by patients, which in turn significantly decreased the most common side effects from colchicine use (*i.e.*, adverse effects involving the gastrointestinal tract, including cramping, nausea, diarrhea, abdominal pain and vomiting);

ii. the discovery of potentially serious drug-drug and food interactions between colchicine and certain foods and drugs, as well as specific dosing regimens that help ameliorate potential negative interactions; and

iii. the development of the more accurate and safer labeling of COLCRYS®, which now lists and warns of numerous drug-drug interactions, food interactions, contraindications, and the potentially dangerous accumulation of colchicine during chronic dosing.

19. These findings and the awareness of the potential health risks associated with colchicine use did not exist prior to Mutual receiving FDA approval for COLCRYS®, and certainly did not exist at the time Mutual was distributing unapproved colchicine.

20. The FDA also required Mutual to include a Medication Guide with COLCRYS®, which includes important warnings regarding various drug-drug interactions and food interactions.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed at Philadelphia, Pennsylvania on August 23, 2010.

/s/ Gregory K. Hayer
GREGORY K. HAYER

EXHIBIT A

Exhibit Filed Under Seal

EXHIBIT B

Exhibit Filed Under Seal